IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF ARKANSAS

MARILYN STUBE and
THOMAS STUBE **PLAINTIFFS**

v. **NO. 6:19-CV-06087-SOH**

PFIZER INC. **DEFENDANT**

REPLY BRIEF IN SUPPORT OF MOTION TO DISMISS

Defendant Pfizer Inc. ("Pfizer") respectfully submits this Reply Memorandum in Support of its Motion to Dismiss Plaintiffs' Complaint pursuant to Federal Rules of Civil Procedure 12(b)(6) and 9(b). After agreeing to dismiss their negligent misrepresentation claim, Plaintiffs now allege five causes of action: (1) strict products liability/failure to warn; (2) fraud and fraudulent inducement; (3) breach of implied warranty; (4) negligence; and (5) gross negligence. For each of Plaintiffs' remaining claims, the relevant facts are not in dispute – only their legal viability, which this Court may decide. For the reasons discussed below and in Pfizer's initial Motion to Dismiss, these claims fail as a matter of law and should be dismissed with prejudice, because the Xeljanz label contains an FDA-mandated black box warning about the very types of infections that can lead to sepsis. As a result, the label is adequate as a matter of law, and any claim that the label should contain a different warning is preempted by federal law. Independent of the adequacy of the label and preemption issues, Plaintiffs' fraud claims and request for punitive damages also should be dismissed.

I. The Warnings in the Xeljanz Label Are Adequate as a Matter of Law.

Because the Xeljanz label adequately warned of the injury Mrs. Stube experienced, Plaintiffs' entire Complaint should be dismissed. The boxed warning for Xeljanz states that "**Patients treated with XELJANZ are at increased risk for developing serious infections**

that may lead to hospitalization or death." Dkt. No. 19-1, at 2. In addition, the Warnings & Precautions section references specifically both infection and sepsis: "**Patients should be closely monitored for the development of signs and symptoms of infection** during and after treatment with XELJANZ. **XELJANZ should be interrupted if a patient develops a serious infection, an opportunistic infection, or sepsis**." *See id*. at 4-5 (emphasis added).[1]

Plaintiffs do not contest that this language appears prominently in the Xeljanz label. Nor do they dispute that sepsis is a well-known consequence of serious infection. *See* Dkt. No. 22, at 4-5. Nor do they contest that Mrs. Stube's serious bacterial infection caused her sepsis. They only contest that the label omitted an intermediate step (sepsis) between a serious infection and hospitalization.

Whether the label is adequate in that regard is a legal question that the Court may decide, not a factual dispute. A label is not inadequate because it does not enumerate all the possible ways that a serious infection can lead to hospitalization and/or death. *See Estate of LaMontagne v. Bristol-Myers Squibb*, 111 P.3d 857 (Wash. Ct. App. 2005) (concluding warning that lactic acidosis could lead to death was adequate where lactic acidosis led to sepsis and then to death); *see also Guevara v. Dorsey Labs., Div. of Sandoz, Inc.*, 845 F.2d 364, 367 (1st Cir. 1998) (concluding that warning on allergic reactions was adequate and did not need to enumerate all possible forms of allergic reaction where plaintiff experienced a skin rash and alleged she was not warned of the *specific kind* of reaction she experienced). Pfizer does not have a legal obligation to remind physicians of widely-known medical facts, including the possible consequences of a severe infection. *See Begley v. Bristol-Myers Squibb Co.*, No. 06-

[1] In addition to the boxed warning, the "Highlights of Prescribing Information" label section also states that "**[s]erious infections leading to hospitalization or death, including tuberculosis and bacterial, invasive fungal, viral, and other opportunistic infections, have occurred in patients receiving XELJANZ.**" *See id.* at 1.

6051(FLW), 2013 WL 144177, at *4 (D. N.J. Jan. 11, 2013) (acknowledging that "drug manufacturers are not obligated to warn prescribing physicians of risks already known to the medical community" because "there is no duty to warn of a risk that is already known by those to be warned" (internal citations and quotation marks omitted)); *see also Woodbury v. Janssen Pharmaceutica, Inc.*, No. 93 C 7118, 1997 WL 201571, at *7 (N.D. Ill. Apr. 10, 1997) ("In other jurisdictions, courts have held that manufacturers are not required to list every danger with the drug."); *Finn v. G.D. Searle & Co.*, 677 P.2d 1147, 1153 (Cal. 1984) (acknowledging that "both common sense and experience suggest that if every report of a possible risk, no matter how speculative, conjectural, or tentative, imposed an affirmative duty to give some warning, a manufacturer would be required to inundate physicians indiscriminately with notice of any and every hint of danger, thereby inevitably diluting the force of any specific warning given").

The cases that Plaintiffs cite are inapposite, particularly given that the Xeljanz warning regarding serious infections appears in a boxed warning, the most serious one available under FDA regulations.[2] The only case Plaintiffs reference where a failure to warn claim involving a boxed warning was *not* found to be adequate as a matter of law at the pleading stage subsequently was dismissed on a motion for summary judgment because plaintiff's prescribing physician testified that "she understood that Enbrel's warnings of infection included all types of infection." *Small v. Amgen, Inc.*, 134 F. Supp. 3d 1358, 1371-1372 (M.D. Fla. 2015), *aff'd*, 723 F. App'x. 722 (11th Cir. 2018). Plaintiffs failed to mention the ultimate result of that case in their Response Brief, *see* Dkt. No. 22, at 7, and they also ignored another case involving the Enbrel label where a different court dismissed the plaintiffs' failure to warn claim pursuant to Rule 12(b)(6) because it found that the broad risk of infection language in the label was adequate

[2] "Special problems, particularly those that may lead to death or serious injury, may be required by the [FDA] to be placed in a prominently displayed box." 21 C.F.R. § 201.57(e) (2003).

as a matter of law. *See Salvio v. Amgen, Inc.*, No. 2:11-CV-00553, 2012 WL 517446, at *6 (W.D. Pa. Feb. 15, 2012) (finding that Enbrel's "broad warning of the risk of infection" which "highlighted some specific risks, i.e. sepsis and tuberculosis" was adequate to warn the plaintiff's physician of the risk of a fungal infection).

Moreover, Plaintiffs' assertion that Pfizer should have warned of the increased risks of serious infections in the elderly and in females similarly should be dismissed because: (1) it is widely known that the elderly are more prone to infection generally[3]; (2) regardless, the Xeljanz label reminds physicians of this fact[4]; and (3) Plaintiffs provide no facts to support a claim that Xeljanz increases the risks of serious infection that might lead to sepsis in females. Pfizer has no duty to warn of widely-known medical facts, such as that the elderly are more prone to infection. *See Begley*, 2013 WL 144177, at *4. Moreover, the only source Plaintiffs cite in their Complaint relating to females shows a *decreased* risk of infection in females compared to males taking Xeljanz. *See* Dkt. No. 19, at 11; *see also* Dkt. No. 2, ¶ 22 (Cohen et al. (2017)).

As a result, the Court should reject Plaintiffs' attempt to skirt the language of the boxed warning and should grant Pfizer's motion. Plaintiffs' efforts to distract by pointing to other portions of the label are insufficient to overcome the clear, bold, boxed warning at the very beginning of the label that Xeljanz can cause serious infections that lead to hospitalization – the exact injury Mrs. Stube experienced. And the Court can reach that decision as a matter of law. Plaintiffs also assert in their Response Brief that Pfizer *does not* contest that Xeljanz caused Mrs.

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[3] *See* CDC, Who is at risk?, https://www.cdc.gov/sepsis/what-is-sepsis.html?s_cid=NCEZID-Sepsis-501 (last visited Sept. 9, 2019).

[4] Throughout the time Mrs. Stube took Xeljanz, the label has cautioned: "As there is a higher incidence of infections in the elderly population in general, caution should be used when treating the elderly." Dkt. No. 19-1, at 14.

Stube's injuries. *See* Dkt. No. 22, at 1. That is certainly not the case – Defendant does not concede causation.

II. Plaintiffs' Claims Are Preempted by Federal Law.

In addition to the adequacy of the label, the Court also may dismiss Plaintiffs' complaint in its entirety as a matter of law because Plaintiffs' claims are preempted. Pfizer cannot unilaterally change its FDA-approved boxed warning on serious infection, hospitalization, and death to add details on the specific type of serious infection and hospitalization that Mrs. Stube experienced. *See* 44 Fed. Reg. 37,434, 37,448 (Jun. 26, 1979). Plaintiffs do not contest that Pfizer could not have changed the boxed warning. *See* Dkt. No. 22, at 8 (citing Dkt. No. 2, ¶ 22 n.15). Plaintiffs' claims with respect to changes to other portions of the label must likewise fail because Plaintiffs in their briefing still fail to allege any "newly acquired information," which would have been necessary for Pfizer to make any unilateral change under the CBE supplement process. *See* 21 C.F.R. § 314.70(c)(6)(iii)(A); *see Utts v. Bristol-Myers Squibb Co.*, 226 F. Supp. 3d 166, 182 (S.D.N.Y. 2016) ("*Utts I*"); *Gibbons v. Bristol-Myers Squibb Co*., 919 F.3d 699, 708-09 (2nd Cir. 2019).

First, Plaintiffs misstate the legal standard applicable to Pfizer's preemption defense. Plaintiffs first must allege the existence of newly acquired information that would have allowed Pfizer to change the label unilaterally using the CBE process *before* the court considers whether there is clear evidence that FDA would have rejected any proposed change. In *Utts v. Bristol-Myers Squibb Co.*, 251 F. Supp. 3d 644 (S.D.N.Y. 2017) ("*Utts II*"), the court explained that there are two stages to the preemption inquiry: "First, a plaintiff must show that newly acquired information exists such that the manufacturer could unilaterally change its label in accordance with the CBE regulation." 251 F. Supp. 3d at 672. Second, "[i]f the plaintiff can prove the

existence of newly acquired information, the manufacturer may still establish an impossibility preemption defense by presenting 'clear evidence' that the FDA would have exercised its authority to reject the labeling change." *Id.* In other words, the "clear evidence" standard Plaintiffs attempt to impose is *not* relevant unless and until there is "newly acquired information" that reveals a risk that is different in kind or of a greater frequency or severity than that disclosed in the label. *See Utts I*, 226 F. Supp. 3d at 179 n.6 (finding the "clear evidence" standard set forth in *Wyeth* was "misinterpret[ed]" by plaintiffs since, as the Supreme Court "explained in *Mensing*, only after a court has found that a manufacturer possessed 'newly acquired information' to support label changes must a manufacturer demonstrate by 'clear evidence' that such proposed changes would nevertheless have been rejected"). And a plaintiff's failure to allege the existence of newly acquired information in a complaint makes it "appropriate to dismiss a claim under Rule 12(b)(6) as preempted." *Id.*; *see also Gibbons*, 919 F.3d at 708-09 (affirming the district court's dismissal of plaintiffs' complaint for failure to state a claim because the plaintiffs "did not provide enough information about the existence of newly acquired information")*; Pliva, Inc. v. Mensing*, 564 U.S. 604, 624 n.8 (2011).

Here, Plaintiffs have not met that first hurdle of alleging "newly acquired information" such that the "clear evidence" portion of the analysis comes into play. As discussed in Pfizer's opening brief, *see* Dkt. No. 19, at 16, articles that Plaintiffs attached as exhibits to their Response Brief do not reflect incidence rates that show that sepsis occurs in patients taking Xeljanz with any greater frequency or severity since its approval. Further, as Plaintiffs noted in their Response Brief, *see* Dkt. No. 22, at 18-19, Pfizer responsibly reported results from its clinical studies in leading journals read by tens of thousands of medical professionals, including the *New England Journal of Medicine* articles cited by plaintiff. *See* Dkt. No. 2, at 9. Indeed, everything

cited in Plaintiffs' Response Brief as "critical" information allegedly withheld from Mrs. Stube's treating physician, *see* Dkt. No. 22, at 21-22, has been provided by Plaintiffs as exhibits to their Complaint and their Response Brief – that is the very definition of publicly available information and the *opposite* of hiding information.[5]

Second, Plaintiffs cannot avoid dismissal on federal preemption grounds by claiming that sepsis is distinct from serious infection. Plaintiffs erroneously contend that sepsis and amputation are "distinct medical events from a serious infection," *see* Dkt. No. 22, at 5. They are not. Sepsis (which is widely known to lead to gangrene and amputation if it is not properly treated, *see* Dkt. No. 19-2, at 3) is a consequence of serious infection; it cannot occur absent an infection. Plaintiffs' own sources define sepsis that way. *See* Dkt. No. 22, at 5 n.7 (citing Singer, et al. "The Third International Consensus Definitions for Sepsis and Septic Shock (Sepsis-3)," *JAMA* 23; 315(8): 802 (Feb. 2016), to "defin[e] sepsis as 'life-threatening organ dysfunction caused by a dysregulated host response to infection'"); *see also Small v. Amgen, Inc.*, 2 F.Supp.3d 1292, 1298 (M.D. Fla. 2014) (finding that the Enbrel label "not only provides a broad and general warning of infection, but also includes warnings regarding specific types of infections ('Infections have included bacterial sepsis and tuberculosis')"). Because Plaintiffs have not identified information regarding sepsis that qualifies as "newly acquired information" that would have enabled Pfizer to make a unilateral change to the Xeljanz label, their Complaint is preempted by federal law and should be dismissed.

[5] For this reason, Plaintiffs' request for punitive damages should also be stricken. Their challenge to the specific contents of the Xeljanz label demonstrates nothing more than their disagreement with FDA's decision-making processes and what types of publicly available information should be included in a label. The Complaint includes no support for the allegation that Pfizer acted recklessly with respect to its communication of the relevant risks as required to support punitive damages. *See Nat'l By-Products, Inc. v. Searcy House Moving Co.*, 292 Ark. 491, 494, 731 S.W.2d 194, 196 (1987).

III. The Learned Intermediary Doctrine Bars Plaintiffs' Claims To The Extent They Are Based on Warnings to Plaintiffs Directly.

In their Response Brief, Plaintiffs argue that the Complaint survives despite the learned intermediary doctrine. They claim, for example, that "[t]he cases cited by Pfizer are readily distinguishable because, unlike this case, they did not involve misrepresentations made directly by the drug company to the patient in advertising materials." Dkt. No. 22, at 20. In support of that claim, Plaintiffs do not actually attempt to distinguish the cases cited in Pfizer's opening. They instead cite *Witczak v. Pfizer, Inc.*, 377 F. Supp. 2d 726 (D. Minn. 2005),[6] for the proposition that allegations concerning "direct marketing initiatives" defeat the learned intermediary doctrine. Under Arkansas law, Plaintiffs are wrong.

Allegedly inadequate warnings form the basis for all causes of action raised in the Complaint. The learned intermediary rule thus applies. *See Hill v. Searle Labs., a Div. of Searle Pharm., Inc.*, 884 F.2d 1064, 1070 n.10 (8th Cir. 1989) (noting that an "[i]nadequate warning [was] relevant to all three causes of action asserted" under Arkansas law). Under the rule, as adopted in Arkansas (as opposed to Minnesota), "a drug manufacturer may rely on the prescribing physician to warn the ultimate consumer of the risks of a prescription drug." *West v. Searle & Co.*, 305 Ark. 33, 42, 806 S.W.2d 608, 613 (1991). Explaining the policy rationales behind the learned intermediary defense, the Arkansas Supreme Court noted:

> [T]he patient must look to the physician, for it is only the physician who can relate the propensities of the drug to the physical idiosyncracies [sic] of the patient. It is the physician who is in the best position to decide when to use and how and when to inform his patient regarding risks and benefits pertaining to drug therapy.

[6] Plaintiffs' reliance on *Witczak* is puzzling. In that case, the court faced a straightforward issue at the summary judgment stage—whether "federal preemption bar[red] plaintiff's state law failure-to-warn claim." *Id.* at 727. The court held that it did not but, in doing so, did not address Minnesota's learned intermediary rule.

Kowalski v. Rose Drugs of Dardanelle, Inc., 2011 Ark. 44, at 17, 378 S.W.3d 109, 120 (quoting *McKee v. Am. Home Prod., Corp.*, 782 P.2d 1045, 1050-51 (1989)) (internal quotation marks omitted).

Plaintiffs' purported "direct" allegations of wrongdoing against Pfizer would require this Court to overturn settled Arkansas law. As explained above (and in Pfizer's opening brief), Pfizer fulfilled its duty by specifically warning of the infection-related risks associated with Xeljanz. Those warnings were communicated *directly to Mrs. Stube's prescribing physician*, who has testified that he "reviewed Pfizer's Xeljanz warnings and professional labeling" at the time he selected the medication for Mrs. Stube. Dkt. No. 22-1, at 1. The prescribing doctor "relied" on those warnings, and he "was aware that serious infection was associated with the use of Xeljanz based upon [his] review [of] the Xeljanz package insert." *Id.* Based on the concessions found on the face of Plaintiffs' pleadings, Mrs. Stube's learned intermediary made a decision to prescribe Xeljanz despite his specific knowledge that the product could cause a "serious infection"—the exact type of injury alleged in this case. The learned intermediary doctrine therefore bars Plaintiffs' claims because it was Mrs. Stube's prescriber who was "'in the best position to decide when to use and how and when to inform [Mrs. Stube] regarding risks and benefits pertaining to'" Xeljanz. *Kowalski*, 2011 Ark. 44, at 17, 378 S.W.3d at 120 (quoting *McKee*, 782 P.2d at 1050-51). Arkansas law thus requires dismissal.[7]

[7] Even if Plaintiffs could assert a claim on the basis that the Xeljanz label did not warn her adequately about the risk of infection, the allegations in the complaint do not pass muster under *Iqbal* and *Twombly*, because the Xeljanz Medication Guide available to Mrs. Stube at the time she took Xeljanz describes the risk of infections in detail. *See* Dkt. No. 19-1, at 31 ("XELJANZ is a medicine that affects your immune system. XELJANZ can lower the ability of your immune system to fight infections. Some people have serious infections while taking XELJANZ, including tuberculosis (TB), and infections caused by bacteria, fungi, or viruses that can spread throughout the body. Some people have died from these infections."). The Medication Guide even notes that living, having lived, or having traveled to certain parts of the country – such as the Ohio and Mississippi River valleys and the Southwest – can increase the risk of getting certain kinds of fungal infections. *See id.* at 31.

IV. Plaintiffs' Fraud Claims Do Not Surpass the Rule 9(b) Standard Established by the Eighth Circuit.

Plaintiffs' fraud claims fare no better. In response to Pfizer's motion to dismiss, Plaintiffs suggest that the Complaint need only "include enough detail to inform the defendant of the 'core' factual basis for the fraud claims." Dkt. No. 22, at 21 (quoting *Commercial Prop. Investments, Inc. v. Quality Inns Int'l, Inc.*, 61 F.3d 639, 646 (8th Cir. 1995)).[8] That oversimplification ignores the great weight of binding case law. The Eighth Circuit requires that a complaint alleging fraud "must identify who, what, where, when, and how." *United States ex rel. Costner v. United States*, 317 F.3d 883, 888 (8th Cir. 2003). Even where a plaintiff can muster only "representative examples" of fraud, he or she must still include "*the time, place, and content of the defendant's false representations, as well as the details of the defendant's fraudulent acts, including when the acts occurred, who engaged in them, and what was obtained as a result*." *United States ex rel. Joshi v. St. Luke's Hosp., Inc.*, 441 F.3d 552, 556-57 (8th Cir. 2006) (emphasis added). Plaintiffs have not done so here.

The decisions cited by Plaintiffs demonstrate the pleading deficiencies in the Complaint. *See* Dkt. No. 22, at 22 n.28. In *Duncan v. Harmon*, the plaintiffs' complaint identified: (1) the identity of the particular person which made the alleged misrepresentation; (2) the specific date on which the alleged fraud occurred (January 28, 2014); (3) the location where the defendant allegedly made the misrepresentation (a home in White County); (4) the specific question posed prior to the alleged misstatement of material fact ("whether [the defendant] was aware of any potential pending changes in the regulation of" a microlending business); and (5) intent on the

[8] Again, Plaintiffs' selection of authority is curious. They cite *Commercial Property Investments, Inc.* for the proposition that the Complaint must only allege the "'core' factual basis for the fraud claims." *See* Dkt. No. 22, at 21. That argument fails because the defendant in the case cited "d[id] not dispute that [the plaintiff] properly pleaded the time, place, and contents of the misrepresentations alleged to be fraudulent." *Commercial Prop. Investments, Inc.*, 61 F.3d at 645. Instead, the defendant's Rule 9(b) argument challenged the district court's admission of evidence regarding misrepresentations that were not pleaded in the plaintiff's complaint. *See id.*

part of the defendant in light of his receipt of a specific letter concerning forthcoming regulatory changes. No. 4:16-CV-00910 BSM, 2017 WL 5071268, at *3 (E.D. Ark. Nov. 2, 2017). Similarly, in C*THC Holdings, LLC v. First Capital Real Estate Investments, LLC*, the plaintiff's complaint alleged: (1) the identity of the person who made the representation under review; (2) the particular date on which the misrepresentation was made (December 2, 2016); and (3) the specific contents of the misrepresentation (that certain partnership interests pledged as collateral for a mortgage "existed, had value, and were liquid at the time Plaintiff entered into the Mortgage"). No. 4:18CV00106 JM, 2018 WL 6787355, at *2 (E.D. Ark. Oct. 9, 2018). The Complaint in the present case lacks such detail. Plaintiffs do not identify the specific Pfizer employee(s) who made "false representations" to Mrs. Stube. Plaintiffs do not provide the dates or locations where the "false representations" were made. And Plaintiffs do not even attempt to allege any of the specific content of the "false representations" at issue, beyond broad allegations concerning "safety data" and "medical literature" that are widely available to the public. Absent those particulars, binding decisions of the Eighth Circuit mandate dismissal of Plaintiffs' fraud-based claims.[9]

V. Plaintiffs Cannot Proceed with a Claim for Punitive Damages.

Finally, at the conclusion of their Response Brief, Plaintiffs briefly address the issue of exemplary damages.[10] Here, Plaintiffs incorrectly argue that "[t]he merits of Pfizer's defense to the punitive damages claim should be reserved for a later stage of the case." Dkt. No. 22, at 23. That argument—and Plaintiffs' exclusive reliance upon *In re Prempro*, 586 F.3d 547, 571 (8th

[9] Plaintiffs concede that the negligent misrepresentation claim must be dismissed. *See* Dkt. No. 22, at 23.

[10] Plaintiffs also side-step Pfizer's request for dismissal of the gross negligence claim, arguing only that they "have sufficiently alleged grossly negligent conduct." *Id.* The Court should reject Plaintiffs' attempt to keep their gross negligence claim alive because the Complaint does not allege, as required by Arkansas law, that Pfizer failed "to use even slight care." *IPSCO Tubulars, Inc. v. Ajax TOCCO Magnathermic Corp.*, 779 F.3d 744, 752 (8th Cir. 2015).

Cir. 2009)—is unavailing. "'Mere negligence, indifference, or careless disregard of the rights of others is not sufficient upon which to base a recovery for exemplary damages.'" *Hoggard v. Arabi Cattle Co.*, No. 3:15CV00323 JM, 2016 WL 1626858, at *2 (E.D. Ark. Apr. 22, 2016) (quoting *Satterfield v. Rebsamen Ford, Inc.*, 253 Ark. 181, 185-86, 485 S.W.2d 192, 195 (1972)) (dismissing a punitive damages claim under Rule 12(b)(6)).

Plaintiffs do not contest the strongly worded warnings found on the Xeljanz label. They instead cite *In re Prempro* to argue that Pfizer cannot "rel[y] on its warning to allege that Plaintiffs' punitive damages claim must be dismissed." Dkt. No. 22, at 23. Not so. *In re Prempro* arose from a bellwether trial in the Prempro litigation, where a female plaintiff alleged that two pharmaceutical manufacturers failed to warn of the risk of developing breast cancer in patients taking hormone replacement therapy drugs. *In re Prempro*, 586 F.3d at 553. In its opinion, the Eighth Circuit reviewed the relevant labeling history of the products in exhaustive detail:

> In 1992, both the physician labeling and patient information sheet for Premarin provided the following warning: "Some studies have suggested a possible increased incidence of breast cancer in those women on estrogen therapy taking higher doses for prolonged periods of time. The majority of studies, however, have not shown an association with the usual doses used for estrogen replacement therapy." The Premarin labeling did not provide any information concerning the combined use of estrogen plus progestin.

Id. at 561. Trial experts testified that the language included in the labels was "confusing," "did not clearly convey a risk to patients," and "falsely implied that [one defendant manufacturer] had conducted studies to analyze the risk." *Id.* at 562. According to the court, Provera – another drug in the class – did not warn of breast cancer at all, and the label simply "informed patients of the results of the study on beagle dogs and concluded that the 'significance with respect to humans has not been established.'" *Id.*

The Xeljanz label could not be more distinguishable. In it, Pfizer specifically warned Mrs. Stube's prescriber that "**Patients treated with XELJANZ are at increased risk for developing serious infections that may lead to hospitalization or death."** Dkt. No. 19-1, at 2 (emphasis in original). The label also states, "**Serious infections leading to hospitalization or death, including tuberculosis and bacterial, invasive fungal, viral, and other opportunistic infections, have occurred in patients receiving XELJANZ**." *Id.* (emphasis in original). Mrs. Stube's prescribing physician was aware of those risks, and he prescribed Xeljanz anyway. Dkt. No. 22-1, at 1. Mrs. Stube then sustained alleged injuries from the exact type of risk—an infection—disclosed in a boxed warning on the Xeljanz label. The punitive damages claims in *In re Prempro* were allowed to proceed due to the absence of allegedly appropriate warnings on the risk of breast cancer. Here, the Xeljanz label included the strongest-possible warning permitted under FDA regulations. As such, Plaintiffs simply have not alleged malice where their Complaint rests upon infection-related risks plainly disclosed on the Xeljanz label. The request for punitive damages should be stricken.

CONCLUSION

For the reasons stated above, Plaintiffs' Complaint should be dismissed in its entirety and with prejudice.

This 11th day of October, 2019.

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